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Date of Approval _____

FREEDOM OF INFORMATION SUMMARY

ANADA 200-299

Indication for use: Ivermectin Pour-On
applied at the recommended dose level of 500mcg/kg
is indicated for the effective control and treatment of these parasites.

Sponsored by:

Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

ANADA 200-299

FOIS-1

FREEDOM OF INFORMATION SUMMARY**1. GENERAL INFORMATION:**

ANADA: 200-299

Sponsor: Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

Generic Name: Ivermectin Topical Liquid

Trade Name: Ivermectin Pour-On for Cattle

Dosage Form: Topical Solution

How Supplied: 8.5 fl oz/250 mL, 33.8 fl oz/1 L, 84.5 fl oz/2.5 L and 3.785 L
(1 gallon) Bottles & 169 fl oz/5 L collapsible pack

How Dispensed: OTC

Amount of Active Ingredients: 5 mg/mL

Route of Administration: Topical, on the dorsal midline, withers to tailhead

Species: Cattle

Labeled Dosage: 500 mcg/kg (1 mL/22 lbs) body weight

Indications for Use: Ivermectin Pour-On applied at the recommended dose level of 500mcg/kg is indicated for the effective control and treatment of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i>	(adults and L ₄)
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)
<i>Cooperia</i> spp.	adults and L ₄)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>O. venulosum</i>	(adults only)
<i>Trichuris</i> spp.	(adults)

Lungworms

Dictyocaulus viviparus (adults and L₄)

Cattle Grubs

(parasitic stages)

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

It is also used to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

Pioneer Product/
"Listed Product:

Ivomec® Pour-On for Cattle (Ivermectin)
NADA 140-841 (Merial Ltd.)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April, 1996).

Based upon the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver on May 11, 1998, from conducting an *in vivo* bioequivalence study for Ivermectin Pour-On for Cattle. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

3. HUMAN FOOD SAFETY:

TOLERANCE:

The tolerances established for the pioneer product apply to the generic product. The marker residue used to monitor the total residues of ivermectin and its metabolites is 22,23-dihydroavermectin B_{1a}. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B_{1a} in liver (target tissue) as follows:

- (i) Cattle: 100 parts per billion [21 CFR 556.344(b)]

A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in muscle as follows:

- (ii) Cattle: 10 parts per billion [21 CFR 556.344(b)]

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for ivermectin pour-on is established under 21 CFR 524.1193(e)(3) - 48 days in cattle.

REGULATORY METHODS FOR RESIDUES

The official analytical method for residues is an HPLC method with fluorescence detection. [The validated regulatory analytical methods for detection of residues of ivermectin are filed in the Food Additives analytical Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fisher's Lane, Rockville, MD 20857) and are on file at the Center for Veterinary Medicine, FDA 7500 Standish Place, Rockville, MD 20855]

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Ivermectin Pour-On for Cattle were established by demonstration of chemical equivalence to the pioneer product, Merial Limited's Ivomec® Pour-On for Cattle (NADA 140-841).

This generic product and the pioneer product have identical labeling indications for use in cattle. The route and method of administration of the two drugs are identical. Both drugs are administered topically. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ivermectin Pour-On for Cattle is safe and effective for its labeled indications when used under its proposed conditions of use.

Attachments:

1. Generic Labeling:

Package Insert

Bottle Label

2. Pioneer Labeling

Package Insert

Bottle Label



09158201



9158201

IVOMEC®
(ivermectin)



pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Introduction

IVOMEC® (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

Indications

IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i>	(adults and L ₄)
(including inhibited stage)	
<i>Haemonchus placei</i>	(adults and L ₄)
<i>Trichostrongylus axei</i>	(adults and L ₄)
<i>T. colubriformis</i>	(adults and L ₄)
<i>Cooperia</i> spp.	(adults and L ₄)
<i>Strongylus papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L ₄)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L ₄)
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Cattle Grubs

<i>Hypoderma bovis</i>	(parasitic stages)
<i>H. lineatum</i>	

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

Dosage

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration***Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)***

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Measure-Pour System (33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

Collapsible Pack (84.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack)

Connect the applicator gun to the collapsible pack as follows:

Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

*IVOMEC and Cattle Head Logo are registered trademarks of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

Mode of Action

Ivermectin as a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-aminobutyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses — thereby paralyzing and killing the parasite.

The enhancement of the GABA effect in arthropods such as mites, lice, and horn flies resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

The principal peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

Safety

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

WARNING! FLAMMABLE!

**KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME,
AND OTHER SOURCES OF IGNITION.**

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain water-borne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Package Information

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle with a squeeze-measure-pour system (Product 41309A), a 33.8 fl oz/1 L bottle with a squeeze-measure-pour system (Product 41310A), or in an 84.5 fl oz/2.5 L collapsible pack (Product 41311A), and a 169 oz/5 L collapsible pack (Product 41350A) intended for use with appropriate automatic dosing equipment.



Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

U.S. Pat 4,199,569
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Whitehouse Station, New Jersey, U.S.A.
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September 1998

Ivomec

pour-on for cattle

Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:

Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT,
SPARKS, OPEN FLAME, AND
OTHER SOURCES OF IGNITION!

WARNING!
NOT FOR USE IN HUMANS.

Merck AgVet Division
Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

Product 41310A

33.8 fl oz (1.06 qt) (1L)

8783102

1007-86 8474E1

1007-86 8474E1

1007-86 8474E1



Ivomec

(ivermectin)
pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills:
Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sticking Lice
Biting Lice
Mange Mites
Horn Flies

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT,
SPARKS, OPEN FLAME, AND
OTHER SOURCES OF IGNITION.

WARNING!
NOT FOR USE IN HUMANS

Lot No & Exp Date ▼
EBJ277
10-2001

Merck AgVet Division
Merck & Co., Inc.
Rahway, N.J., 07065-0912, U.S.A.

Product **41309A**

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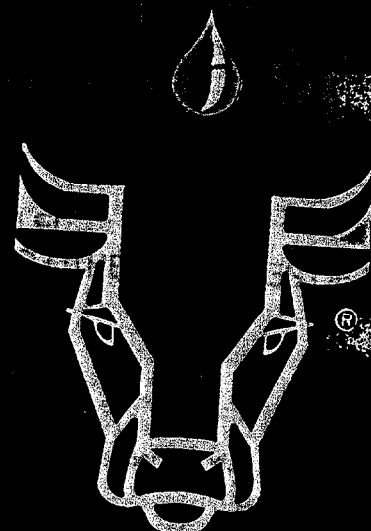
8.5 fl oz (250 mL)

Ivomec®

(ivermectin)

Pour-on for cattle

Contains 5 mg
ivermectin/mL



Parasiticide

Kills:

Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies



MERCK

AgVet Division

Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

Product 41350A

8865900

169 fl.oz (5L)

IVOMEC

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS:

Treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

CAUTIONS:

Keep away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Seal container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

For application to skin surface only. Do not give orally or parenterally.

Unless in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 40°F.

Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

IVOMEC Pour-On has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Lot No. & Exp. Date

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Lot No. & Exp. Date

1.0 L (2.64 qt)(2.5L)

1350A

EBJ239

08-2001



Ivomec[®]

(ivermectin)

pour-on for cattle

Contains 5 mg
ivermectin/mL

Parasiticide

Kills:

Roundworms
(including Brown Stomach Worm)
Lungworms
Grubs
Sucking Lice
Biting Lice
Mange Mites
Horn Flies

Product 41311A

8778101



Merck & Co., Inc.
Rahway, New Jersey, 07065-0912, U.S.A.

84.5 fl oz (2.64 qt) (2.5 L)

FB 1249

08-200

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS:

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

PRECAUTIONS:

Keep away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Seal container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing the product to warm to room temperature will restore the normal appearance without affecting efficacy.

The parasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or crusts, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Pat. 4,199,569

U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of
Pfizer Inc., Whitehouse Station, N.J., U.S.A.

Lot No & Exp Date ▼

E3J271

OCT00

5 fl oz (5 L)

ANADA 200-299, Approved by FDA.

IVERMECTIN POUR-ON For cattle

Contains 5 mg ivermectin/mL

Parasiticide

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Introduction:

Ivermectin Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, Ivermectin Pour-On contains ivermectin, a unique chemical entity.

Indications:

Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)
<i>Haemonchus placei</i>	(adults and L4)
<i>Trichostrongylus axei</i>	(adults and L4)
<i>T. colubriformis</i>	(adults and L4)
<i>Cooperia</i> spp.	(adults and L4)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L4)
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Cattle Grubs

<i>Hypoderma bovis</i> <i>H. lineatum</i>	(parasitic stages)
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Mites

<i>Sarcoptes scabiei</i> var. <i>bovis</i>
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Lice

<i>Linognathus vituli</i> <i>Haematopinus eurysternus</i> <i>Damalinia bovis</i> <i>Solenopotes capillatus</i>

Horn Flies

<i>Haematobia irritans</i>

Persistent Activity

Ivermectin Pour-On has been proved to effectively control infections and to protect cattle from reinfection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

Ivermectin Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermectin Pour-On should be part of a parasite control program for both internal and

external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

Dosage

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration

Squeeze-Measure-Pour System (8.5 fl. oz/250 mL Bottle with 25 mL Measuring Cup).

Measure the amount of solution to be used at the dose rate of 1 mL for each 22 lb of body weight into the measuring cup. When body weight is between markings use the higher setting.

Tilt the measuring cup to deliver the dose.

Squeeze-Measure-Pour System (33.8 fl. oz/1 L Bottle with 25 mL Measuring Cup).

Measure the amount of solution to be used, at the dose rate of 1 mL for each 22 lbs of body weight, into the measuring cup. When body weight is between markings, use the higher setting.

Tilt the measuring cup to deliver the dose.

One Gallon Bottle and Collapsible Pack (84.5 fl oz/ 2.5 L Pack and 169 fl oz/5 L Pack)

Connect the applicator gun to the collapsible pack as follows: Attach the open end of the draw-off tubing to the dosing equipment. Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

Mode of Action

Ivermectin as a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-amino-butyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses - thereby paralyzing and killing the parasite.

The enhancement of the GABA effect in arthropods such as mites, lice and horn flies resembles that in roundworms except that nerve impulses are interrupted between the nerve ending and the muscle cell. Again, this leads to paralysis and death.

Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

The principle peripheral neurotransmitter in mammals, acetylcholine, is unaffected by ivermectin. Ivermectin does not readily penetrate the central nervous system of mammals where GABA functions as a neurotransmitter.

Safety

Studies conducted in the USA have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

WARNING! NOT FOR USE IN HUMANS.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION.

PRECAUTIONS

Store away from excessive heat (104° F/ 40° C) and protect from light.

- Use only in well-ventilated areas or outdoors.
- Close container tightly when not in use.
- Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
- Do not use when rain is expected to wet cattle within six hours after treatment.
- This product is for application to skin surface only. Do not give orally or parenterally.
- Cloudiness in the formulation may occur when Ivermectin Pour-On is stored at temperatures below 32° F. Allowing to warm at

room temperature will restore the normal appearance without affecting efficacy.

- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, ivermectin Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

Ivermectin Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with ivermectin Pour-On at the end of the fly season may be re-treated with ivermectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain waterborne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Package Information

Ivermectin Pour-On is available in an 8.5 fl oz./ 250 mL bottle, a one gallon/3.785 L container, a 33.8 fl oz/1 L bottle, an 84.5 fl oz/ 2.5 L collapsible pack and a 169 fl oz/5 L collapsible pack intended for use with appropriate automatic dosing equipment.

Med-Pharmex Inc.
Pomona, CA 91767, USA
November 2000.

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WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION.

PRECAUTIONS

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- Close container tightly when not in use.
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Cattle treated with ivermectin Pour-On at the end of the fly season may be re-treated with ivermectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

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Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain waterborne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Package Information

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Med-Pharmex Inc.
Pomona, CA 91767, USA
November 2000.

ANADA 200-299, Approved by FDA.

IVERMECTIN POUR-ON For cattle

Contains 5 mg ivermectin/mL

Parasiticide

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Introduction:

Ivermectin Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, Ivermectin Pour-On contains ivermectin, a unique chemical entity.

Indications:

Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)
<i>Haemonchus placei</i>	(adults and L4)
<i>Trichostrongylus axei</i>	(adults and L4)
<i>T. colubriformis</i>	(adults and L4)
<i>Cooperia</i> spp.	(adults and L4)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L4)
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Cattle Grubs

<i>Hypoderma bovis</i> <i>H. lineatum</i>	(parasitic stages)
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Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

Ivermectin Pour-On has been proved to effectively control infections and to protect cattle from reinfection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

Treatment of Cattle for Horn Flies

Ivermectin Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermectin Pour-On should be part of a parasite control program for both internal and

external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

Dosage

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration

Squeeze-Measure-Pour System (8.5 fl. oz./250 mL Bottle with 25 mL Measuring Cup).

Measure the amount of solution to be used at the dose rate of 1 mL for each 22 lb of body weight into the measuring cup. When body weight is between markings use the higher setting.

Tilt the measuring cup to deliver the dose.

Squeeze-Measure-Pour System (33.8 fl. oz./1 L Bottle with 25 mL Measuring Cup).

Measure the amount of solution to be used, at the dose rate of 1 mL for each 22 lbs of body weight, into the measuring cup. When body weight is between markings, use the higher setting.

Tilt the measuring cup to deliver the dose.

One Gallon Bottle and Collapsible Pack (84.5 fl oz/ 2.5 L Pack and 169 fl oz/5 L Pack)

Connect the applicator gun to the collapsible pack as follows: Attach the open end of the draw-off tubing to the dosing equipment. Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

Mode of Action

Ivermectin as a member of the avermectin family kills certain parasitic roundworms and ectoparasites, such as mites, lice, horn flies and other insects. Its action is unique to the avermectin class of antiparasitic agents. This action involves a chemical that serves as a signal from one nerve cell to another, or from a nerve cell to a muscle cell. This chemical, a neurotransmitter, is called gamma-amino-butyric acid or GABA.

In roundworms, ivermectin stimulates the release of GABA from nerve endings and enhances binding of GABA to special receptors at nerve junctions, thus interrupting nerve impulses - thereby paralyzing and killing the parasite.

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Ivermectin has no measurable effect against flukes or tapeworms, presumably because they do not have GABA as a nerve impulse transmitter.

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Safety

Studies conducted in the USA have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

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Keep this and all drugs out of the reach of children.

WARNING! FLAMMABLE!
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PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

- Use only in well-ventilated areas or outdoors.
- Close container tightly when not in use.
- Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
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When to Treat Cattle with Grubs

Ivermectin Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with ivermectin Pour-On at the end of the fly season may be re-treated with ivermectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain waterborne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Package Information

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Med-Pharmex Inc.
Pomona, CA 91767, USA
November 2000.

ANADA 200-299, Approved by FDA.

IVERMECTIN POUR-ON For cattle

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Introduction:

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Indications:

Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i> (including inhibited stage)	(adults and L4)
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<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichuris</i> spp.	(adults)

Lungworms

<i>Dictyocaulus viviparus</i>	(adults and L4)
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Cattle Grubs

<i>Hypoderma bovis</i> <i>H. lineatum</i>	(parasitic stages)
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Mites

<i>Sarcoptes scabiei</i> var. <i>bovis</i>
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Lice

<i>Linognathus vituli</i> <i>Haematopinus eurysternus</i> <i>Damalinia bovis</i> <i>Solenopotes capillatus</i>

Horn Flies

<i>Haematobia irritans</i>

Persistent Activity

Ivermectin Pour-On has been proved to effectively control infections and to protect cattle from reinfection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

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Dosage

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration

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Tilt the measuring cup to deliver the dose.

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Tilt the measuring cup to deliver the dose.

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Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

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Med-Pharmex Inc.
Pomona, CA 91767, USA
November 2000.

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 169 fl oz (5 Liters)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

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Recommended Dose:

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This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 169 fl oz (5 Liters)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

**IVERMECTIN POUR-ON
for cattle**

Contains: 5 mg ivermectin/mL

**INTERNAL and EXTERNAL
PARASITICIDE for CATTLE**

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open
Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: One Gallon (3.785 L)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

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Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: One Gallon (3.785 L)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: One Gallon (3.785 L)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON
for cattle

Contains: 5 mg ivermectin/mL

**INTERNAL and EXTERNAL
PARASITICIDE for CATTLE**

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!

Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 84.5 fl oz (2.5 Liters)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:

1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

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This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 84.5 fl oz (2.5 Liters)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32° F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
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Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:
1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

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Store away from excessive heat (104°F/40°C) and protect from light.

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

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This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

PRECAUTIONS:

Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL
**INTERNAL and EXTERNAL
PARASITICIDE for CATTLE**

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 33.8 fl oz (1 Liter)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL
**INTERNAL and EXTERNAL
PARASITICIDE for CATTLE**

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 33.8 fl oz (1 Liter)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

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Pomona, CA 91767

ANADA # 200-299 Approved by FDA

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This product is for application to skin surface only. Do not give orally or parenterally.

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Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

IVER-ON™

IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL
**INTERNAL and EXTERNAL
PARASITICIDE for CATTLE**

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 33.8 fl oz (1 Liter)

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Pomona, CA 91767

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This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:
1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention. Keep this and all drugs out of the reach of children.

PRECAUTIONS:
Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™ IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 8.5 fl oz (250 mL)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:
1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention. Keep this and all drugs out of the reach of children.

PRECAUTIONS:
Store away from excessive heat (104°F/40°C) and protect from light.

IVER-ON™ IVERMECTIN POUR-ON for cattle

Contains: 5 mg ivermectin/mL

INTERNAL and EXTERNAL PARASITICIDE for CATTLE

Kills:

Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies.

WARNING: Flammable!
Keep Away From Heat, Sparks, Open Flame and Other Sources of Ignition.

WARNING: Not For Use In Humans.

Net Contents: 8.5 fl oz (250 mL)

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

MP MED-PHARMEX, INC.
Pomona, CA 91767

ANADA # 200-299 Approved by FDA

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVER-ON is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g. caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVER-ON is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers.

Dispose of containers in an appropriate landfill or by incineration.

Lot # / Exp. Date

Indications: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose:
1 mL per 22 lb of body weight.

WARNING: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention. Keep this and all drugs out of the reach of children.

PRECAUTIONS:
Store away from excessive heat (104°F/40°C) and protect from light.

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